

Remarks

Claims 1-13 are presented for the Examiner's review and consideration. In this Response, claims 1, 3, 5-8, 10 and 12 are amended. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §112 Rejections

Claims 3 and 12 were rejected under 35 U.S.C. §112, first paragraph. The rejection stated that, with respect to the cited claims, while the specification was enabling for "protecting", it was not enabling for "preventing". Accordingly, Applicant has amended claims 3 and 12 herein to remove reference to preventing.

Claims 1-13 were rejected under 35 U.S.C. §112, second paragraph. With respect to claims 5-8 and 10, the limitation "preferably" was cited as rendering the claims indefinite. Accordingly, Applicant has amended the cited claims to positively recite a range. The term "about" was added to the upper range, because the original intent of the claims was to specify a minimum quantity, and a preferred quantity, wherein an upper boundary was not specifically set. As stated in the specification, the intake of one bar per day suffices to ensure the lasting improvement of the cognitive functional capacity; however, it is also possible to eat several bars per day. (§[0025]).

With respect to claims 1, 5 and 7, the limitation "cognitive functional capacity" was cited with respect to the metes and bounds of the claim being unclear. Accordingly, Applicant has amended claims 1, 5 and 7 to alternatively recite "improving the cognitive function of the brain of the food consumer".

Applicant respectfully submits that the amendments do not introduce new matter.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the §112 rejections.

35 U.S.C. §103 Rejection

Claims 1-13 were rejected under 35 U.S.C. §103(a), as being unpatentable over Lang et al. (US pub no. 2003/0161861 A1) (“Lang”) in view of Strumor et al. (US Patent No. 6,149,939) (“Strumor”). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Lang

Lang discloses the use of a cereal product such as a biscuit or cracker having a slowly digestible starch content relative to the total starch content higher than about 12 wt %, preferably higher than about 20 wt %, to improve cognitive performances, in particular memory retention, attention, concentration, vigilance and/or mental well-being in people, and particularly in a child and an adolescent. (Abstract).

As stated in Lang: Unexpectedly, the applicants have shown that the regulation of the glycemic index, alone, was insufficient to increase these performances. (¶[0017]). The applicants have now demonstrated that certain cereal products significantly improve cognitive performance, by virtue of the choice of appropriate proportions between slowly digestible starch and the total starch present in the product. (Id). These products may have, moreover, moderate lipid levels. (Id).

The rats which consumed a biscuit-based breakfast were more calm, whereas the rats which consumed a breakfast based on ready-to-eat cereals were more active and show signs of distress (more passages in the central compartment, this indicating higher distress since the behavior of crossing a room along the diagonal rather than along the walls is unusual in rats). (¶[0073]). It is obvious that only the bioavailability of starch makes it possible to explain these differences in results. (¶[0074])

The two groups of rats respectively consume a breakfast composed of biscuits according to the present invention and cereals. (§[0080]). The products used are balanced with respect to the supply of carbohydrates. (§[0081])

As such, Lang discloses improving cognitive performance by consuming a breakfast combining certain proportions of slowly digestible starch with respect to the total starch of the meal. As noted in the rejection, Lang does not disclose or suggest the use of phosphatidyl serine.

Strumor

Strumor discloses stable tablets and mini-bars which dissolve in the mouth and are capable of supplying needed healthful agents. (Col. 2, Ins. 2-3). A wide variety of active ingredients is useful in the tablets and mini-bars of this invention. (Col. 2, Ins. 21-22). Of particular use, are active ingredients which are suitable for daily health conditions and those ingredients which are needed by victims of disaster to keep them alive and functioning until professional help arrives. (Id).

Strumor discloses 16 ingredients as useful for aiding memory, including 50mg of Phosphatidyl serine complex. There is otherwise no discussion of phosphatidyl serine complex in the specification. There is mentioned about 180 different ingredients which could be incorporated into the dissolvable product of Strumor.

As such, Strumor does not disclose a dosage of phosphatidyl serine complex greater than 50mg. Further, there is no disclosure or suggestion in Strumor to combine phosphatidyl serine with carbohydrates.

Present Invention

In contrast, the present invention discloses a food item, preferably a bar of chocolate, that has a phosphatidyl serine content of 100 mg to 300 mg and a relatively high carbohydrate content. (Abstract).

The starting point of the present invention is the discovery that, in older individuals, the intake of 100 mg to 300 mg of phosphatidyl serine per day can lead to an improvement of the cognitive functional capacity, in particular the memory and learning capacity, and to an increase in the powers of concentration and attentiveness. (§[0012]).

Preferably, the food product according to the present invention has a relatively high carbohydrate content, such as fructose syrup, sugar and/or glucose syrup. (§[0020]). By specifically combining the intake of carbohydrates and phosphatidyl serine, the glucose intake, and thus the glucose content in the brain cells, is markedly increased. (Id). In the short term, this makes possible an especially marked increase in the cognitive functional capacity. (Id). The minimum quantity of carbohydrates is preferably 15 g combined with preferably 100 to 300 mg of phosphatidyl serine. (Id).

Eating one or more of the chocolate bars every day in the short term leads to an increase in the cognitive functional capacity after consumption of the bar, on the one hand, and in the long term to a lasting improvement of the cognitive functions which begins to be noticeable, for example, after a period of one to three weeks. (§[0053]). Thus, improvements both with respect to ARCD [Age Related Cognitive Decline] and with respect to AAMI [Age Associated Memory Impairment] can be reached. (Id).

As such, the present invention discloses a relationship between phosphatidyl serine and glucose intake in the brain. The combination is further found in the present invention to improve cognitive function shortly after consumption, as well as lasting improvements over time. These novel results are not suggested in the prior art.

As stated above, Lang does not disclose the use of phosphatidyl serine to improve cognitive ability. More particularly, Lang is directed to a specific ratio of slowly digestible starch to total starch, and thus does not suggest a combination of starch with any other material.

Strumor includes phosphatidyl serine in a large list of possible beneficial materials which could be provided in dissolvable form to individuals in an emergency. There is no suggestion in Strumor to combine phosphatidyl serine with carbohydrates, particularly as there is no

discussion of phosphatidyl serine at all. Further, there is no discussion of carbohydrates in Strumor.

The present invention includes at least two novel elements, neither of which are present in the prior art. First, that a dosage of at least 100mg of phosphatidyl serine is effective to produce improved cognitive functional capacity. Strumor discloses 50mg of phosphatidyl serine, however Applicants have found that 50 milligrams produces no measureable effect. Indeed, it does not appear likely that Strumor performed any experiments with respect to the efficacy of phosphatidyl serine, in light of the large number of materials listed, and the lack of discussion of particular clinical results. More particularly, Strumor is directed primarily to a mode of delivery for any of a wide variety of materials. In addition, as phosphatidyl serine is not mentioned in Lang, this element is entirely absent in the reference.

The second novel element is an unexpected beneficial result of the combination of at least 100 milligrams of phosphatidyl serine combined in food with a relatively high carbohydrate content. Specifically, Applicant observed a marked increase in glucose intake, with concomitant beneficial results in cognitive function.

Both of these elements are claimed in the present invention, and neither is disclosed or suggested by the prior art. There is no motivation to combine the references, for as Strumor shows in part, there are numerous substances thought to have a beneficial effect on memory, and indeed, the amount of experimentation required to identify the unexpected results of a combination of phosphatidyl serine and a relatively high carbohydrate content would not only not be suggested, but would also be unreasonably extensive. Further a combination including at least 100 milligrams of phosphatidyl serine is not suggested in the prior art.

In addition, Applicant respectfully suggests that the combination of Strumor and Lang is improperly based on hindsight. Not only is the combination not suggested in either reference, but the addition of a significant quantity of phosphatidyl serine might disrupt the balanced combination of slowly digestible starch and total starch in Lang. Indeed, rats were shown to be distressed by ready-to-eat cereal, and the addition of phosphatidyl serine or other chemical could

serve to mask the ratio sought in Lang. Similarly, the addition of carbohydrates in Strumor could disrupt the desired storage ability and dissolvability sought in Strumor.

Amended claim 1, recites, a food for improving the cognitive function of the brain of the food consumer containing a minimum of 100 mg of phosphatidyl serine, and with a minimum of 15 g of carbohydrates. Remaining independent claims 5 and 7 contain similar recitations.

Accordingly, Applicant respectfully submits that claims 1, 5 and 7 are patentable over Lang in view of Strumor. As claims 2-4 depend from claim 1, and claims 6 and 8-13 depend from claim 5, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the §103 rejection.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7390-X03-018)

Respectfully submitted,

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